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California Department of Public Health



EDMUND G. BROWN JR.
Governor

November 19, 2015

TO: LABORATORIES THAT PERFORM HIV TESTING

SUBJECT: ESTABLISHMENT OF STATE ELECTRONIC LABORATORY REPORTING SYSTEM FOR HIV

The California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA) has leveraged and adopted the existing state electronic laboratory reporting (ELR) system to establish a state electronic laboratory reporting system for reporting HIV-related test results as of November 2, 2015. Laboratory reports of HIV infection generated pursuant to California Health and Safety Code (HSC) Section [121022\(a\)](#) must be reported electronically within one year of the establishment of a state electronic laboratory reporting system per HSC Section [120130\(g\)](#).

HSC Section [121022\(a\)](#) requires laboratories to report confirmed cases of HIV infection to the local health officer, and CDPH OA is authorized to access electronic submissions of these reports. Laboratories are required to confirm all reactive or indeterminate HIV test results per 17 California Code of Regulations (CCR) Section [1230](#). A “confirmed HIV test” is defined broadly in 17 CCR Section [2641.30](#) as “a procedure which verifies the presence of HIV infection as determined by any clinical laboratory test or HIV Test Algorithm or examination used to detect the presence of HIV, a component of HIV, or antibodies to or antigens of HIV, including the HIV antibody (HIV-Ab), HIV p-24 antigen, Western blot (Wb), and immunofluorescence antibody tests; or . . . all tests used to monitor HIV infection, including HIV nucleic acid detection.” All CD4+ T-Cell test results related to HIV infection are required to be reported per HSC Section [121023](#).

The ELR system is capable of receiving all HIV-infection-related test results that verify the presence of HIV (including, but not limited to: EIA; Western blot; antibody differentiation tests, such as Multispot/Geenius; NAT; viral load, including undetectable results; and HIV genotype sequences) or that are used to monitor HIV infection (including, but not limited to, CD4+ T-cell count and percent and viral load) in Health Level-7 (HL7) version 2.5.1 format as defined by the [HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 \(US Realm\)](#), with additional guidance provided in the [CalREDIE HL7 2.5.1 ELR2PH Companion Guide](#). HL7 version 2.3.1 legacy format is also accepted for HIV, but this format may not satisfy federal requirements for Meaningful Use. Messages formatted in HL7 2.5.1 with LOINC and SNOMED vocabulary is required for submitters handling HIV along with other

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laboratory results reportable to public health under 17 CCR Section [2505](#). Information about the required HL7 version 2.3.1 segments and elements is available on our website: <http://www.cdph.ca.gov/programs/aids/Pages/TOASurv.aspx>. The supported method of data transport is a secure web service Simple Object Access Protocol (SOAP) over secure Hypertext Transfer Protocol Secure (https).

Production ELR messages are validated by OA and routed to the appropriate California local health jurisdiction. The process for a laboratory to transition through ELR testing and into ELR production can take a little as 90 days. The process consists of CDPH testing of ELR message structure and content, followed by field testing involving a comparison of ELR results to those received through standard delivery methods at the local level. If the message volume and content are found to be comparable during field testing, the local health jurisdictions are asked to approve the laboratory for production ELR, after which reporting HIV test results delivered solely through ELR satisfies the statutory and regulatory reporting requirements for HIV test results.

To start the process of reporting HIV-related results through ELR, contact the [CDPH HIE Gateway](#) to register for a submitter account. For other HIV ELR-related questions, contact Scott Masten, Chief of the HIV Surveillance Section at OA, at (916) 449-9231 or Scott.Masten@cdph.ca.gov.

Sincerely,



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Chief, Office of AIDS
California Department of Public Health

cc: Local AIDS Directors, all California LHJs
HIV Surveillance Coordinators, all California LHJs
California Public Health Laboratory Directors
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Dr. Juliana Grant, Chief, HIV Surveillance, Research & Evaluation Branch
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